



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/577,698

04/28/2006

Bhunja Debnath

DRF33029

3725

70554

7590

12/05/2008

Reddy Us Therapeutics, Inc
3065 Northwoods Circle
Norcross, GA 30071

EXAMINER

MCDOWELL, BRIAN E

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

12/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/577,698		DEBNATH ET AL.	
	Examiner		Art Unit	
	BRIAN MCDOWELL		1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-76 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 28-76 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ia where B = a bond, and Ar = naphthalene or tetrahydronaphthalene.
- II. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ia where B = a bond, and Ar = tetrahydroquinoline which is attached at the nitrogen position.
- III. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ia where B = a bond, and Ar = indole or indoline which is attached at the nitrogen position.
- IV. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ib where B = a bond, and Ar = naphthalene or tetrahydronaphthalene.

Art Unit: 1624

- V. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ib where B = a bond, and Ar = tetrahydroquinoline which is attached at the nitrogen position.
- VI. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ib where B = a bond, and Ar = indole or indoline which is attached at the nitrogen position.
- VII. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ic where B = a bond, and Ar = naphthalene or tetrahydronaphthalene.
- VIII. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ic where B = a bond, and Ar = tetrahydroquinoline which is attached at the nitrogen position.
- IX. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ic where B = a bond, and Ar = indole or indoline which is attached at the nitrogen position.
- X. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Id where B = a bond, and Ar = naphthalene or tetrahydronaphthalene.
- XI. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Id where B = a bond, and Ar = tetrahydroquinoline which is attached at the nitrogen position.

- XII. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Id where B = a bond, and Ar = indole or indoline which is attached at the nitrogen position.
- XIII. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Id where B = O and Ar = phenyl.
- XIV. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ie where B = a bond, and Ar = naphthalene or tetrahydronaphthalene.
- XV. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ie where B = a bond, and Ar = tetrahydroquinoline which is attached at the nitrogen position.
- XVI. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula Ie where B = a bond, and Ar = indole or indoline which is attached at the nitrogen position.
- XVII. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula If where B = a bond, and Ar = naphthalene or tetrahydronaphthalene.
- XVIII. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula If where B = a bond, and Ar = tetrahydroquinoline which is attached at the nitrogen position.

- XIX. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula If where B = a bond, and Ar = indole or indoline which is attached at the nitrogen position.
- XX. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula If where B = O, and Ar = phenyl.
- XXI. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof of the formula If where B = a bond, and Ar = a benzoxazine ring (includes oxo compound) attached at the nitrogen position.
- XXII. Claims 28-61 and 63-70 (in part), drawn to compounds and simple compositions thereof not embraced by groups I-XXI.
- XXIII. Claim 62, drawn to a process of making either of the compounds described in groups I-XXII (applicant must chose one group of compounds).
- XXIV. Claims 71-72, drawn to a method of treating diabetes and dyslipidemia using compounds in either groups I-XXII (applicant must chose one group of compounds).
- XXV. Claims 75-76, drawn to medicines encompassing compounds in either groups I-XXII (applicant must chose one group of compounds).

Note: A single disclosed chemical specie is required for any group elected.

In addition, claims 73-74 are not considered due to non-statutory use claims and are withdrawn from consideration. Cancellation of these claims is recommended.

The inventions listed as Groups I-XXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The prior art by Bhuniya *et al.* (WO 03/033481, see example 11, page 91), which is mentioned in the ISR, teach a compound that anticipates claim 29. Therefore, the compounds and methods are not novel and the invention lacks a special technical feature.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone

Art Unit: 1624

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624